REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

Status of the Claims

Pending claims

Claims 1 to 4, 6 to 10 and 12 to 21 are pending in the application.

Outstanding Rejections and Objections

Claims 4 and 10 are objected to. Claims 1 to 3, 6 to 9 and 12 to 21 are rejected under 35 U.S.C. §112, first paragraph, enablement requirement. Claims 1 to 4, 6 to 10 and 12 to 21, are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1 to 4, 7 to 9 and 13 to 16, of co-pending USSN 10/098,874. Claims 1, 7 and 17 are rejected under 35 U.S.C. §112, first paragraph, written description requirement.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the Claim Amendments

Support for the amended claims can be found throughout the application's disclosure in the specification and claims as filed; see also this application's publication U.S. Patent Application Publication serial no. 20040247621, which published December 9, 2004 ("the '621 publication"). Accordingly, Applicants submit that no new matter is introduced by the present amendments.

Issues under 35 U.S.C. §112, first paragraph

Enablement Requirement

The rejection of claims 1 to 3, 6 to 9 and 12 to 21 under 35 U.S.C. §112, first paragraph, enablement requirement, is maintained for reasons set forth on pages 2 to 3 of the OA.

The Office has acknowledged that the specification is enabling for a combination of a reshaped PM-1 antibody and melphalan (see e.g., page 2, first sentence of this section, in the OA).

However, the Office alleges the specification does not enable any other combination (i.e., other than a combination of a reshaped PM-1 antibody and melphalan) (see e.g., page 2, first sentence of this section, in the OA). It is alleged, *inter alia*, because that the art of finding synergy between two anti-cancer drugs are unpredictable, and that synergy can be found only by experimentation in this unpredictable art, undue experimentation would be needed to practice the full scope of the claimed invention (see e.g., lines 15 to 19, page 3, of the OA).

However, Applicants respectfully aver that by enabling a combination of a reshaped PM-1 antibody and melphalan (as acknowledged by the Office), the specification is also enabling for a combination of melphalan and any antibody having the same activity/ same mechanism of action as reshaped PM-1 antibody. Data showing synergy between melphalan also predicts synergy between melphalan and any antibody having the same mechanism of action as PM-1 antibody. Thus, the data set forth in the specification experimentally confirms an anti-cancer synergistic effect between melphalan and a compound that inhibits IL-6 signaling, e.g., experimentally confirms an anti-cancer synergistic effect between melphalan and an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6, including but not limited to PM-1. The significance of the data is that the synergistic effect is provided by a combination of melphalan and inhibition of IL-6 signaling – an effect not limited to melphalan and PM-1.

One of skill in the art at the time of the invention would have reasonably expected that because PM-1 inhibits IL-6 signaling by binding to the IL-6 receptor, any compound having the same anti-IL-6 receptor effect, i.e., an inhibitory effect on the IL-6 receptor, would also act synergistically with melphalan. Thus, because it would not have taken undue experimentation to identify anti-IL-6 receptor antibodies that inhibit signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor, and because these antibodies can, analogous to PM-1, act with melphalan to have an anti-cancer synergistic effect, the specification sufficiently enables the full scope of the claimed invention, and the section 112, first paragraph, enablement rejection can be properly withdrawn.

Issues of nonstatutory obviousness-type double patenting

Claims 1 to 4, 6 to 10 and 12 to 21, are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1 to 4, 7 to 9 and 13 to 16, of co-pending USSN 10/098,874, as discussed on page 4 of the OA.

Applicants will hold this issue in abeyance until such time claims are held allowable.

Provisional rejection under 35 U.S.C. §112, written description

Claims 1, 7 and 17 are rejected under 35 U.S.C. §112, first paragraph, written description requirement, as discussed on page 5 of the OA. This is a new "new matter" rejection.

The instant amendment addresses this issue.

Objections to the claims

Claims 4 and 10 are objected to, as discussed on page 5, of the OA. The instant amendment addresses this issue.

CONCLUSION

It is believed that the all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance is respectfully requested.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 350292000402. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By /Gregory P. Einhorn/
Gregory P. Einhorn
Registration No.: 38,440
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 720-5133 direct line
general office 858 720 5100
fax direct 858 523 5933
fax office 858 720 5125

email geinhorn@mofo.com